

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF  
PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE  
THE GENERAL CAUSATION OPINION OF STEPHEN LAGANA, M.D.**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' opposition to Defendants' motion to exclude the general causation opinion of Stephen Lagana, M.D.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of Internal Agency for Research on Cancer, *Some N-Nitroso Compounds*, in *IARC Monogr. Eval. Carcinog. Risk Chem. Hum.*, 107, 152 (Lyon, Fr. 1978).
3. Attached hereto as **Exhibit 2** is a true and accurate copy of FDA, *FDA presents interim limits of nitrosamines in currently marketed ARBs* (Dec. 19, 2018), <https://tinyurl.com/4rkpdf5h>.
4. Attached hereto as **Exhibit 3** is a true and accurate copy of EPA, *N-Nitrosodimethylamine*, <https://tinyurl.com/9krh69u9>.

5. Attached hereto as **Exhibit 4** is a true and accurate copy of EPA, *N-Nitrosodiethylamine*, <https://tinyurl.com/48y7nejw>.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of the relevant excerpt of the USP, Summary, Highlights and Timeline of General Chapter <1469> Nitrosamine Impurities (July 20, 2018).

7. Attached hereto as **Exhibit 6** is a true and accurate copy of Tricker & Preussmann, *Carcinogenic N-nitrosamines in the diet: occurrence, formation, mechanisms and carcinogenic potential*, MUTATION RESEARCH 259, 277-89 (1991).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of White, *Understanding and Preventing (N-Nitrosodimethylamine) NDMA Contamination of Medications*, THE ANNALS OF PHARMACOTHERAPY 54, 611-4 (2020).

9. Attached hereto as **Exhibit 8** is a true and accurate copy of SOLCO00024226 (ZHP 129).

10. Attached hereto as **Exhibit 9** is a true and accurate copy of the relevant excerpt of PRINSTONO0075850.

11. Attached hereto as **Exhibit 10** is a true and accurate copy of the relevant excerpt of the April 22, 2021 deposition transcript of Min Li.

12. Attached hereto as **Exhibit 11** is a true and accurate copy of the relevant excerpt of the April 29, 2021 deposition transcript of B.V. Ramarao.

13. Attached hereto as **Exhibit 12** is a true and accurate copy of the relevant excerpt of the April 30, 2021 deposition transcript of B.V. Ramarao.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of Dr. Stephen Lagana's CV.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of Funkhauser, *Pathology: The Clinical Description of Human Disease*, in *Molecular Pathology*, p. 197-207, 197, 203 (Elsevier, Inc. 2009).

16. Attached hereto as **Exhibit 15** is a true and accurate copy of London, Michalec, Mehdi, Zhu, Kerchner, Sanyal, Viswanathan, Pfahnl, Shang, Madhusudanan, Baty, Lagana, Aleong, Gutmann, Ackerman, McNamara, Weiss, Dudley, *Mutation in glycerol-3-phosphate dehydrogenase 1 like gene (GPD1-L) decreases cardiac Na<sup>+</sup> current and causes inherited arrhythmias*, CIRCULATION. 116, 2260-8 (Nov. 2007).

17. Attached hereto as **Exhibit 16** is a true and accurate copy of Rubinstein, Baik, Lagana, Han, Raab, Sahoo, Dalerba, Wang, Han, *Fusobacterium nucleatum promotes colorectal cancer by inducing Wnt/ $\beta$ -catenin modulator Annexin A1*, EMBO REP. 20 (Apr. 2019).

18. Attached hereto as **Exhibit 17** is a true and accurate copy of Van Treeck, Mounajjed, Moreira, Orujov, Allende, Bellizzi, Lagana, Davila, Jessen, Graham, *Transcriptomic and Proteomic Analysis of Steatohepatic Hepatocellular Carcinoma Reveals Novel Distinct Biologic Features*, AM. J. CLIN. PATHOL. 155, 87-96 (Jan. 2021).

19. Attached hereto as **Exhibit 18** is a true and accurate copy of Lagana, Parwani, & Nichols, *Cardiac sarcoidosis: a pathology-focused review*, ARCH. PATHOL. LAB. MED. 134, 1039-46 (Jul. 2010).

20. Attached hereto as **Exhibit 19** is a true and accurate copy of Liteplo & Meek, *Concise International Chemical Assessment Document 38 – N-Nitrosodimethylamine* (WHO 2002).

21. Attached hereto as **Exhibit 20** is a true and accurate copy of *Geiss v. Target Corp.*, No. 09–2208 (RBK/KMW), 2013 WL 4675377 (D.N.J. 2013).

22. Attached hereto as **Exhibit 21** is a true and accurate copy of *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, Case No. 2:14-MD-02592, Doc 6198, 2017 WL 1352860 (E.D. La, Apr. 13, 2017).

23. Attached hereto as **Exhibit 22** is a true and accurate copy of *Glynn v. Merck Sharp & Dohme Corp.*, Nos. 11–5304, 08–08, 2013 WL 1558690 (D.N.J. Apr. 10, 2013).

24. Attached hereto as **Exhibit 23** is a true and accurate copy of the relevant excerpt of the deposition transcript of Dr. Stephen Lagana from the *Benicar* MDL.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of *In re Avandia Marketing, Sales Practices & Products Liab. Litigation*, No. 2007–MD–1871, 2011 WL 13576 (E.D. Pa., Jan. 4, 2011).

26. Attached hereto as **Exhibit 25** is a true and accurate copy of Al-Kindi & Oliveira, *Abrupt Increase in Reporting of Neoplasms Associated with Valsartan After Medication Recall*, CIRCULATION CARDIOVASCULAR QUALITY AND OUTCOMES (July 2019).

27. Attached hereto as **Exhibit 26** is a true and accurate copy of American Heart Association, *Circulation: Cardiovascular Quality & Outcomes* (stating, “Research Letters will be peer reviewed in a manner identical to original research articles”), <https://tinyurl.com/vh4cn4tr>.

28. Attached hereto as **Exhibit 27** is a true and accurate copy of WHO, *International Agency for Research on Cancer (IARC) - Summaries & Evaluations: N-NITROSODIMETHYLAMINE* (Mar. 27, 1998), <https://tinyurl.com/yzbu8jxd>.

29. Attached hereto as **Exhibit 28** is a true and accurate copy of the relevant excerpt of September 14, 2021 Deposition Transcript of Daniel Catenacci.

30. Attached hereto as **Exhibit 29** is a true and accurate copy of Thresher, Foster, Ponting, Stalford, Tennant, & Thomas, *Are all nitrosamines concerning? A review of mutagenicity and carcinogenicity data*, REGULATORY TOXICOLOGY AND PHARMACOLOGY 116, 2 (2020).

31. Attached hereto as **Exhibit 30** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02–3216(RBK), 2006 WL 166452 (D.N.J. January 20, 2006).

32. Attached hereto as **Exhibit 31** is a true and accurate copy of the relevant excerpt of the May 7, 2021 deposition transcript of Lance Molnar.

**MAZIE SLATER KATZ & FREEMAN, LLC**  
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: December 1, 2021